

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/284,421	06/11/99	GORDON	J 043601/0110 <i>IPPC</i>

IM22/0726

DAVID J. OLDENKAMP, ESQ.
OPPENHEIMER WOLFF & DONNELLY LLP
2029 CENTURY PARK EAST, SUITE 3800
LOS ANGELES CA 90067

EXAMINER

BEX, P

ART UNIT	PAPER NUMBER
1743	<i>14</i>

DATE MAILED: 07/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)	
09/284,421	GORDON, JOHN FRANCIS	
Examiner	Art Unit	
P. K. Bex	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 May 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 45-104 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 45-104 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on 14 May 2001 is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

1. The cancellation of claims 1-44 and the addition of claims 45-104 is acknowledged and has been entered into the record.

Drawings

2. The corrected or substitute drawings were received on May 14, 2001. The changes to the drawings have been approved by the examiner.
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plate structure which includes *digitally encoded address information*, as recited in claims 70, 74, 83, 87, 98, 103 and *the device having an optical inspection type format* as recited in claims 71, 75, 84, 88, 99, 104 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 70-71, 83-84, 87-88, 98-99, 103-104 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 71, 84, 88, 99 and 104 introduce the new limitation wherein the plate structure is provided for use with a device having an optical inspection type format. However, this new limitation is not believed to be adequately supported within the instant specification. The

specification describes the use of a *second embodiment* which depicts the multi-well assay plate in the form of a *disk* 32 designed for use with a rotating scanning device having a CD player type format. This disk 32 is shown in Fig. 3. Additionally one of the surfaces of the upper or lower plates 34, 36 may be provided with digitally encoded address information which can be read by the scanned light beam. The specification does not support the use of such a rotating scanning device having a CD player type format for use with the embodiments which are *not* in the form of a disk as recited in claim 45, 79, 85, 89 and 100, see page 12, line 21- page 13, line 25.

Claims 70, 83, 87, 98 and 103 introduce the new limitation wherein the plate structure is provided with digitally encoded information. As discussed above, the specification describes only the use of a *second embodiment* which depicts the multi-well assay plate in the form of a *disk* 32 provided with digitally encoded address information.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 45-76, 81 and 85-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45, line 4, the phase “small” is a relative phase which renders the claim indefinite. The phase “sufficiently small” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. How “small” is sufficient?

Claim 51, line 2, the phase "similar liquid injecting device" is indefinite. It is not clear as to what applicant considers a "similar liquid injecting device".

Claim 58, line 3, "both directions" lacks antecedent basis. Which directions is applicant referring to? No reference axis is provided. Same deficiency was found in claim 97.

Claim 63, line 2, "its" is vague and indefinite as to what element it refers to. Same deficiency was found in claim 68 and 100.

Claim 66, line 3, the conditional term "can" is not a positive recitation, therefore, renders the claim indefinite.

Claim 71, line 2, the use of the word "type" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Additionally, it is not clear as to what applicant means by an "optical inspection type format" or an "optical reader type format" or a "disc type format"? See claims 75,84, 88, 99 and 104.

Claim 72, line 4, the phase "sufficiently shallow" is a relative phase which renders the claim indefinite. How "shallow" is sufficient? Same deficiency was found in claim 85.

Claim 81, line 1, "the first fluid" lacks antecedent basis.

Claim 102, line 2, "automated fluid handling apparatus" lacks antecedent basis. It is suggested that --an-- be placed before "automated fluid handling apparatus" for clarity.

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1),

(2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 45-50, 52, 77, 79-81, 85-86, 89-91 and 100-101 are rejected under 35 U.S.C. 102(e) as being anticipated by Inoue *et al* (USP 5,955,352).

Inoue *et al* teach a multi-well assay disc plate comprising; a first upper surface 1, a second lower surface 21 having a plurality of wells 3 disposed therein, the first and second surfaces defining a chamber having an inlet and outlet which allows fluids to be introduced and withdrawn from the chamber, the wells being proportioned and dimensioned to retain a volume of fluid in each well following withdrawal of the liquid (column 2, lines 3-9, column 13, line 15-column 16, line 50, Figs. 11-17).

10. Claims 45, 49, 53-54, 57, 71, 79-81, 85-86, 89-91 and 100-101 are rejected under 35 U.S.C. 102(e) as being anticipated by Croteau *et al* (USP 5,700,655).

Croteau *et al* teach a multi-well assay disc plate 10 comprising; a first upper surface 14, a second lower surface having a plurality of wells 12 disposed therein, the first and second surfaces defining a chamber having an inlet 22 and outlet 24 which allows fluids to be introduced and withdrawn from the chamber, the wells being proportioned and dimensioned to retain a volume of fluid in each well following withdrawal of the liquid (column 4, line 52- column 6, line 60, Fig. 2A-4B).

Claim Rejections - 35 USC § 103

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 51, 53-76, 82-84, 87-88, 92-99 and 102-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue *et al* (USP 5,955,352) in view of Merkh *et al* (USP 5,281,540).

Inoue *et al* as discussed previously, do not teach a plate structure which is divided into sectors with a handle at the longer arc-portion to facilitate locating the sector on a disc. However, such a handle is considered conventional in the art, see Merkh *et al*. Merkh *et al* do teach a plate structure which is divided into sector inserts 80 comprising wells 84 and a handle at the longer arc-portion with a information panel 96 which functions to facilitate locating the sector insert on a disc 18(Figs. 1-2, 4-5). Such a handle allows the operator to access patient information corresponding to the particular assay sector insert (column 10, line 60- column 11, line 21). Note that Merkh *et al* also teach sectors inserts and a disc which include lock 100, 102, 104 and key 93 portions to allow the sectors to be snap-fitted in the correct orientation and the disc comprising plurality of dividing walls 122. Additionally, Merkh *et al* teach the sector insert having digitally encoded address information 94 for use with a device having an optical inspection means 316 (column 30, line 51- column 32, line 54, Fig. 14)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the assay apparatus of Inoue *et al* the handle means, as taught by Merkh *et al*, in order allow the operator to access patient information corresponding to the particular assay sector.

Response to Arguments

13. Applicant's arguments filed May 14, 2001 have been fully considered but they are not persuasive. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references, see page 12, paragraph 3 in the REMARKS section of the response.

Conclusion

14. No claims allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For official papers after mailing of a Final Office Action, use fax number (703) 305-3599. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex
P. Kathryn Bex
Patent Examiner
AU 1743
07/24/01

Arlen Soderquist
ARLEN SODERQUIST
PRIMARY EXAMINER